REMARKS

In the Office Action dated September 25, 2003, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121 and §372, alleging that the subject matter defined by the claims of the present invention represents the following five separate and distinct inventions:

I. Claims 1-3, 6-8 and 20, drawn to an animal or avian species modified through non-transgenic mechanisms to have reduced levels of Bcl-w protein.

II. Claims 1-3 and 6-8 10, 11, 14-16 and 20, drawn to a genetically modified animal or a avian species having reduced levels of Bcl-w protein as an effect of a non-Bcl-w transgene or transgene encoding a Bcl-w antisense molecule.

III. Claims 1-3, 9, and 12-20, drawn to a genetically modified animal or avian species having reduced levels of Bcl-w protein as an effect of a genetically modified, endogenous Bcl-w gene.

IV. Claims 1, 4, 5 and 20, drawn to an animal or avian species modified through non-transgenic mechanisms to have reduced levels of a Bcl-w associated protein

V. Claims 1, 4, 5, 14, 15 and 18, drawn to a genetically modified animal or avian species having reduced levels of a Bcl-w-associated protein as an effect of a non-Bcl-w transgene.

The Examiner alleges that the above-identified groups of inventions are not linked to form a single general inventive concept under PCT Rule 13.1, allegedly because these groups lack the same or corresponding special features under PCT Rule 13.2. Specifically, the Examiner contends that the above-identified groups do not fall within the allowed combinations of groups of inventions under MPEP§1850 that would satisfy the unity requirement. In the Examiner's opinion, Groups I-V represent different products with distinct material compositions and uses.

The Examiner contends that Groups I and II encompass animals modified through non-transgenic mechanisms to alter the levels of a Bcl-w protein (Group I) or a Bcl-w associated protein (Group II). According to the Examiner, animals encompassed by these groups can include those administered with drugs or those altered by some other means that does not alter the genetic make-up of the animal. The Examiner further contends that Groups III-V encompass transgenic animals with an altered genome. Group III includes animals with an altered endogenous Bcl-w gene, whereas Group IV encompasses animals with alteration in a gene other than Bcl-w or with a transgene encoding a Bcl-w antisense molecule. Group V encompasses transgenic animals having reduced levels of a Bcl-w associated protein. Furthermore, the Examiner alleges that there is no shared or corresponding technical feature among the claimed inventions of Groups I-V. Specifically, the Examiner contends that Groups I and IV are directed to methods of affecting a Bcl-w related protein, wherein the special technical feature is a Bcl-w associated protein; whereas Groups II-V are directed to methods of affecting Bcl-w, wherein the special technical feature is Bcl-w.

Furthermore, the Examiner states that claims 2, 3, 12 and 20 read on patentably distinct Groups drawn to multiple SEQ ID Numbers. The Examiner contends that SEQ ID Nos. 1-5 and 7 are patentably distinct, because each of the sequences are unrelated, as such a further restriction is applied to the sequences. Therefore, the Examiner requires Applicants to elect a single nucleotide sequence and the corresponding polypeptide sequence.

In order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group III, Claims 1-3, 9 and 12-20, drawn to a genetically modified animal or avian species having reduced levels

of Bcl-w protein as an effect of a genetically modified endogenous bcl-w gene. Applicants further provisionally elect, with traverse, SEQ ID NO: 3, directed to a murine Bcl-w nucleotide sequence, and SEQ ID NO: 4, directed to the murine Bcl-w polypeptide sequence encoded by SEQ ID NO: 3, in response to the Sequence Election Requirement.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression "technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

Applicants submit that Groups I-V are not distinct as the Examiner has alleged, but rather represent one single inventive concept warranting examination in a single application. More specifically, the present inventors uniquely recognized, *inter alia*, that an animal or an avian species deficient for Bcl-w or a gene associated with Bcl-w fails to undergo productive spermatogenesis and is fertile without showing any other major abnormality. Therefore, the present invention provides animals or avian species modified to have reduced levels of a Bcl-w protein (Groups I-III) or have reduced levels of a protein associated with Bcl-w (Groups IV-V).

Groups I-III are merely directed to various means that can be employed to achieve the reduction of levels of a Bcl-w protein. Groups IV-V are directed to various means that can be employed to achieve the reduction of levels of a protein associated with Bcl-w. Applicants respectfully submit that Groups I-V are embodiments linked to each other under the single inventive concept that an animal or an avian species deficient for Bcl-w or a gene associated with Bcl-w fails to undergo productive spermatogenesis. Applicants respectfully submit that Groups I-V are merely different aspects of a single invention.

As to the sequences, SEQ ID NO: 1 and SEQ ID NO: 3 set forth human and murine Bcl-w nucleotide sequences, respectively. The two sequences share a significant degree of identity. The corresponding protein sequences, as set forth in SEQ ID NO: 2 and SEQ ID NO: 4, also share a significant degree of identity and apparently perform similar functions. SEQ ID NO: 5 and SEQ ID NO: 7 set forth nucleotide sequences of derivatives of human Bcl-w and murine Bcl-w, respectively. Clearly, all these sequences are related to each other, both structurally and functionally, as different aspects of a single invention.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of

an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Accordingly, it is respectfully submitted that claims 1-20 satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups and sequences, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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